

<i>Safety Data Sheet</i> NICKEL TITANIUM MATERIAL	DOC. :	SGI
	CODE:	SDS02
	UNIT RESP.:	Quality
	PAGE:	Page 1 of 8
	REVIEW:	00

1. Product and Company Identification:

1.1. **Product Name:**

Contour NiTi Archwire; Aesthetic Contour NiTi Archwire; Contour NiTi Bio Slide Archwire; Super Elastic NiTi Archwire, Aesthetic Super Elastic NiTi Archwire; NiTi Reverse Curve Archwire, Aesthetic NiTi Reverse Curve Archwire; Thermal NiTi Archwire; Aesthetic Thermal NiTi Archwire; Thermal NiTi Reverse Curve Archwire; Aesthetic Thermal NiTi Reverse Curve Archwire; Memoflex Bio Slide Archwire; Thermal Memoflex Bio Slide Archwire; EasyClip Archwire Sequence; EasyClip+ Archwire Sequence; Aesthetic EasyClip+ Archwire Sequence; EasyClip+ BioSlide Archwire Sequence; BioClip Archwire Sequence; Aesthetic BioClip Archwire Sequence; BioClip Bio Slide Archwire Sequence; NiTi Open Coil Spring; Aesthetic NiTi Open Coil Spring; NiTi Closed Coil Spring; Aesthetic NiTi Closed Coil Spring; Niti Distalizing Coil Spring; Aesthetic Niti Distalizing Coil Spring; NiTi Retraction Coil Spring; Aesthetic NiTi Retraction Coil Spring; NiTi Retraction Coil Spring MI (TAD); NiTi Expander; NiTi Rotator; NiTi Wire; NiTi Separator; EasyClip Clips; BioClip Clips.

1.2. **Material:**

Nickel-Titanium (NiTi)

1.3. **Restrictions on Use:**

Products are used for the treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist.

- **Only qualified professionals are allowed to use it:** Federal law restricts the use of this device to, or on the order of, dentists or orthodontists.
- **Single use:** The product is recommended to be used only once, since when it is removed, chemical products can affect the material and the instruments used can apply a force that may change the product geometry, resulting in deformations.

1.4. **Company Information:**

Aditek do Brasil Ltda.
 Rua Cesário Motta, 14
 Cravinhos – SP - Brazil
 CEP: 14140-000
 Phone: +55 16 3951 9355
 E-mail: aditek@aditek.com.br
 Site: www.aditek.com.br

Only available during office hours: 8:30AM – 5:30PM (Brasilia Time)

<i>Safety Data Sheet</i> NICKEL TITANIUM MATERIAL	DOC. :	SGI
	CODE:	SDS02
	UNIT RESP.:	Quality
	PAGE:	Page 2 of 8
	REVIEW:	00

2. **Hazards Identification:**

Solid metallic products are generally classified as “articles” and do not constitute a hazardous materials in solid. Any articles manufactured from these solid products would be generally classified as non-hazardous. However some hazardous elements contained in these products can be emitted under certain processing conditions such as but not limited to: burning, melting, cutting, sawing, brazing, grinding, machining, milling, and welding. Products in the solid state present no fire or explosion hazard. Small chips, fines, and dust may ignite readily, though. The following classification information is for the hazardous elements which may be released during processing.

2.1. **Label Elements:**

Labelling according to EN 980:2008, EN 1041:2008, ISO 15223-1:2015.

2.2. **Signal Word(s): Warning (Nickel):**

Hazard Statements:

- Causes eye irritation
- May cause allergy or asthma symptoms or breathing difficulties if inhaled;
- May cause an allergic skin reaction;
- Suspected of causing genetic defects;
- Suspected of causing cancer;
- Causes damage to organs (kidneys, respiratory system);
- Causes damage to organs through prolonged or repeated exposure (respiratory system);
- Very toxic to aquatic life;
- Very toxic to aquatic life with long lasting effects.

Supplemental Hazard information (EU):

- Do not breathe dust/fume/gas/mist/vapors/spray;
- In case of inadequate ventilation wear respiratory protection;
- Contaminated work clothing should not be allowed out of the workplace;
- Wash thoroughly after handling;
- Wear protective gloves;
- Obtain special instructions before use;
- Do not handle until all safety precautions have been read and understood;
- Use personal protective equipment as required;
- Do not eat, drink or smoke when using this product;
- Avoid release to the environment.

Response

- **IF exposed or concerned:** Get medical advice/attention;
- **IF INHALED:** If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing;

Safety Data Sheet NICKEL TITANIUM MATERIAL	DOC. :	SGI
	CODE:	SDS02
	UNIT RESP.:	Quality
	PAGE:	Page 3 of 8
	REVIEW:	00

- **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical advice/attention;
- **If experiencing respiratory symptoms:** Call a POISON CENTER or doctor/physician;
- **IF ON SKIN:** Wash with plenty of soap and water;
- **If skin irritation or rash occurs:** Get medical advice/attention. Wash contaminated clothing before reuse;
- **If exposed or concerned:** Get medical advice/attention;
- Collect spillage.

Storage

Store it in a cool and dry place, maintaining it in its own package.

Disposal

The product composition does not require specific procedures for transporting it and does not present any risks to people.

3. Composition / Information On Ingredients:

Nickel Titanium NiTi #4								
Chemical Composition Limits (%)								
Ni	C	Co	H	Nb	Cu	Cr	Fe	Ti
54.5 to 57.0	≤ 0.05	≤ 0.05	≤ 0.005	≤ 0.025	≤ 0.01	≤ 0.01	≤ 0.05	Remaining

Nickel Titanium NiTi #1				
Chemical Composition Limits (%)				
Ni	C	H	O	Ti
54.5 to 57.0	≤ 0.05	≤ 0.005	≤ 0.05	Remaining

Other trace elements may also be present in minute amounts. These small quantities (less than 0.1%) are frequently referred to as “trace” or “residual” elements; generally they originate in the raw material used.

4. First-Aid Measures:

No first aid required for contact with solid product. The following information applies to contact from processing:

- **Inhalation:** Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Consult a physician;
- **Skin Contact:** Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician;

<i>Safety Data Sheet</i> NICKEL TITANIUM MATERIAL	DOC. :	SGI
	CODE:	SDS02
	UNIT RESP.:	Quality
	PAGE:	Page 4 of 8
	REVIEW:	00

- Eye Contact: Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Consult a physician;
- Ingestion/Swallowing: Do NOT induce vomiting. Call a physician or Poison Control Center immediately. Drink plenty of water. Never give anything by mouth to an unconscious person.

5. Fire and Explosion Hazards:

5.1. General Fire Hazards:

See Section 9 for Flammability Properties.

This product does not present fire or explosion hazards as shipped. Small chips, fines, and dust from processing may be explosive or readily ignitable.

5.2. Hazardous Combustion Products:

Thermal decomposition can lead to release of irritating gases and vapors. In the event of fire and/or explosion do not breathe fumes. May cause sensitization by inhalation and skin contact.

5.3. Extinguishing Media

Class D extinguishing agents on fines, dust or molten metal. Use coarse water spray on chips and fines.

5.4. Unsuitable Extinguishing Media

DO NOT use halogenated extinguishing agents on small chips or fines. DO NOT use water for fires involving molten metal. These fire extinguishing agents will react with burning material.

5.5. Fire Fighting Equipment/Instructions

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES:

6.1. General:

No notable environmental hazard is anticipated from the “release” of this material in bulk solid form on land. This material should be recovered from aquatic environments.

6.2. Recovery and Neutralization:

Avoid dust formation. Collect scrap for recycling.

<i>Safety Data Sheet</i> NICKEL TITANIUM MATERIAL	DOC. :	SGI
	CODE:	SDS02
	UNIT RESP.:	Quality
	PAGE:	Page 5 of 8
	REVIEW:	00

6.3. Materials and Methods for Clean-Up:

If product is molten, contain the flow using dry sand or salt flux as a dam. All tools and containers which come in contact with molten metal must be preheated or specially coated and rust free. Allow the spill to cool before remelting as scrap.

6.4. Emergency Measures

Keep people away from and upwind of spill/leak.

6.5. Personal Precautions and Protective Equipment

Wear appropriate protective clothing and respiratory protection for the situation.

6.6. Environmental Precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not flush into surface water or sanitary sewer system.

7. HANDLING AND STORAGE:

7.1. Handling, storage and decontamination procedures:

Avoid contact with skin, eyes, and clothing. Wear personal protective equipment when handling.

Avoid dust creation. Keep material dry. Avoid contact with sharp edges, corners, hot metal.

Good housekeeping must be practiced during storage, transfer, handling and use to avoid excessive dust accumulation.

7.2. Incompatible Products:

May react in contact with strong acids to release gaseous acid decomposition products, e.g. hydrogen, oxides of nitrogen. Use of strong oxidizers (high pH) on stainless steel may cause Cr (VI) compounds to form at ambient temperatures. Decomposition: Fumes generated during welding, brazing, or thermal cutting may contain: chromium compounds, including hexavalent chromium Cr (VI); nickel; manganese; iron; molybdenum; and silicon compounds.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION:

8.1. Control Parameters:

Exposure Guidelines: Chemicals are not readily available as they are bound within the alloy. Occupational exposure limits apply to some components resulting from grinding, polishing, abrasive blasting, hot rolling, hot forging, thermal cutting, or welding which may produce nickel titanium dust or fumes.

<i>Safety Data Sheet</i> NICKEL TITANIUM MATERIAL	DOC. :	SGI
	CODE:	SDS02
	UNIT RESP.:	Quality
	PAGE:	Page 6 of 8
	REVIEW:	00

8.2. Exposure Controls:

Appropriate Engineering Controls:

Ensure adequate ventilation, especially in confined area (i.e. showers, eyewash stations, etc.).

Personal Protective Equipment:

Eye & Face Protection:

When processing the metal alloy wear: Tightly fitting safety goggles.

Skin Protection:

When processing the metal alloy: Wear protective gloves/clothing.

Respiratory Protection:

If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations.

Respiratory protection must be provided in accordance with current local regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES:

9.1. Basic Physical & Chemical Properties:

- Appearance: Silver or Black Wire;
- Odor: None
- pH: N/A
- Melting Point/Freezing Point: 1981°F/ 1083°C
- Flash Point: N/A
- Evaporation Rate: N/A
- Flammability (solid, gas): N/A
- Vapor Pressure: N/A
- Vapor Density: N/A
- Relative Density: N/A
- Solubility(ies): Insoluble in H₂O

9.2. Other Information:

None

10. STABILITY AND REACTIVITY:

Reactivity:

None Known

Chemical Stability:

Stable

<i>Safety Data Sheet</i> NICKEL TITANIUM MATERIAL	DOC. :	SGI
	CODE:	SDS02
	UNIT RESP.:	Quality
	PAGE:	Page 7 of 8
	REVIEW:	00

Conditions of Instability:

None Known

Possibility of Hazardous Reactions:

None Known

Conditions to Avoid:

Dust formation

Incompatible Materials:

Acids, oxidizing agents, ammonium nitrate, sulfur, alkalies, selenium, nickel nitrate, sodium azide.

Hazardous Decomposition Products

Toxic metal fumes and oxides emitted when product is heated above the melting point.

Hazardous Polymerization

Will not occur.

11. TOXICOLOGICAL INFORMATION:

In its solid form stainless steel does not present an inhalation, absorption, or ingestion hazard. Grinding, polishing, abrasive blasting, hot rolling, hot forging, thermal cutting, or welding may produce stainless steel dust or fumes containing complex or mixed oxides of its components. Metal dust particles may cause eye, skin and/or respiratory system irritation. The below information is for these instances.

- **Serious Eye Damage/Irritation:** Dust or fines may cause mechanical irritation;
- **Respiratory/Skin Sensitization:** Dust may cause skin irritation May cause allergic skin reaction (sensitization);
- **Ingestion:** No acute effects expected from swallowing small amounts;
- **Carcinogenicity:** Nickel compounds (may be formed in welding) are classified by IARC as known human carcinogens (Group 1) and by NTP as “Known Human Carcinogens”. Metallic nickel is classified by IARC as possibly carcinogenic to humans (Group 2B) and by NTP as “Reasonably Anticipated to be a Carcinogen”;
- **Aspiration Hazard:** Dust or fumes may cause irritation of the mucous membranes and upper respiratory tract May cause allergic respiratory reaction (sensitization);
- **Medical Conditions Generally Aggravated by Exposure:** Individuals with pre-existing skin disorders may be at increased risk from exposure.

<i>Safety Data Sheet</i> NICKEL TITANIUM MATERIAL	DOC. :	SGI
	CODE:	SDS02
	UNIT RESP.:	Quality
	PAGE:	Page 8 of 8
	REVIEW:	00

12. ECOLOGICAL INFORMATION:

Chemicals are not readily available as they are bound within the alloy.

13. DISPOSAL CONSIDERATIONS:

The generator of waste material has the responsibility for proper waste classification, transportation and disposal with accordance applicable federal, state/provincial and local regulations.


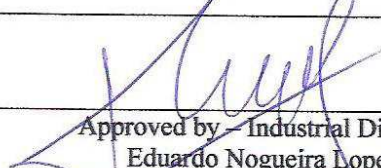
14. TRANSPORTATION INFORMATION:

DOT Not Regulated

15. REVIEW HISTORY:

First version.

Date: 10/2016

	
Elaborated by – Quality Manager Alex Forastier Pierini	Approved by – Industrial Director Eduardo Nogueira Lopes